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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,436	06/30/2003	Istvan Toth	4050.002900	9341

23720 7590 07/14/2005

WILLIAMS, MORGAN & AMERSON, P.C.
10333 RICHMOND, SUITE 1100
HOUSTON, TX 77042

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,436	TOTH ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/18/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-17 and 19 in the reply filed on 2/18/2005 is acknowledged.

Claims 18 and 20-23 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/18/2005.

Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8 should recite the proper Markush language "selected from the group consisting of". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, formula I, the component D is not shown as directly linked to [Wq-S-X-L]. This indicates that D and [Wq-S-X-L] are present as two separate components. The claim recites that it is a compound. It is not clear what applicants intend. For the purpose of prosecution formula I is interpreted to mean either a single compound wherein D and [Wq-S-X-L] are linked

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or a composition comprising D and [Wq-S-X-L] as ingredients. The claim recites that D is a therapeutically useful molecule. The metes and bounds of this recitation are not clear. Any molecule will be considered as a therapeutically useful molecule. The claim recites that the linker group may be substituted. In the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

In claims 2 and 14, it is not clear what "sugar-amino conjugate" and "pro-drug or drug-like molecule" means. For the purpose of prosecution it is interpreted as any molecule that is therapeutically useful.

In claims 4 and 6 it is not clear what glycosidic position means. Do applicants mean through the anomeric position? For the purpose of prosecution it is interpreted as any position on the saccharide.

In claim 11 one of the Markush members recited for a charged functional group is amine. An amine group by itself is not charged. It becomes charged if the nitrogen of the amine forms a fourth bond with another atom. It is not clear what applicants intend. For the purpose of prosecution it is interpreted as a group that can be charged.

In claim 12 it is not clear what the recitation "in which the mono- or oligosaccharide S is a mono-, di- or trisaccharide" means. According to the claim recitation, a monosaccharide and an

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oligosaccharide are both being defined as a mono-, di- or a trisaccharide. The claim recitation is confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dekany et al (Peptides, 1996, 331-32).

Dekany et al disclose a lipidic moiety containing sugar compound (page 332, structural formula 2). In this structure the lipidic moiety (shown to the right in the structure; L in instant claim 1) is attached to a monosaccharide (S in the instant claims) via a linker (NH group). The sugar bearing the lipidic moiety is attached to another sugar. The second sugar moiety constitutes the therapeutically useful molecule D in the instant claims. A sugar molecule is a therapeutically useful molecule. Since formula I doesn't show a bond between D and the rest of the molecule and since claim 1 is drawn to a compound, it is interpreted that D is attached to the rest of the molecule via a covalent bond. This meets the limitations of claim 1 for W being absent and the overall molecule being neutral.

Since D is a sugar in structure 2 of Dekany, and a sugar is a drug-like molecule and also a biological molecule (found in biosystems) the structure meets the limitations of claims 2-4. The linker, NH in structure 2, is attached to the sugar unit through the glycosidic position (limitation of claim 4). The term glycosidic position is not defined by the claim. Hence any position on the

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sugar moiety is interpreted as a glycosidic position. Since the attachment of the lipidic moiety to the sugar is via a nitrogen atom and a CONH group is present, the attachment to the monosaccharide is via an N-glycoside and an amide bond (limitations of claim 5 and 6). The linker, NH, is attached to the lipidic moiety $\text{C(O)CH-(NHR}^2\text{)-(CH)}_2\text{-CH}_3$ group in structure 2 of Dekany) via an amide bond (limitation of claim 7). In structure 2 of Dekany lipidic moiety L is composed of the group $\text{-C(O)CH-(NHR}^2\text{)-(CH)}_2\text{-CH}_3$. This structure is same as structure IIa for R_1 = hydrogen and R_2 = linear alkyl chain having 16 carbons and both R_1 and R_2 are not hydrogens at the same time (limitation of claim 9). The lipid moiety in structure 2 of Dekany has an NHR^2 group attached to it, which can be charged (meets limitations of claims 10-11). In structure 2 of Dekany the sugar unit in the middle (mono saccharide) is attached to a lipidic moiety containing one lipoaminoacid meeting the structural formula IIa in instant claim 12.

Conclusion

Claims 1-17 and 19 are rejected

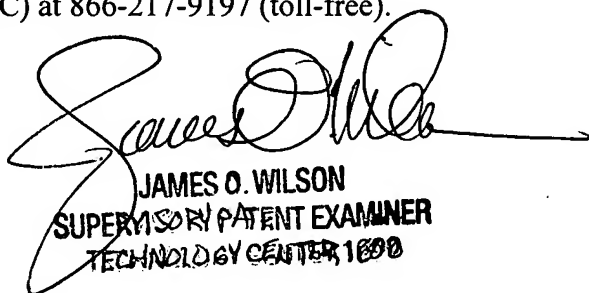
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600